



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,823	06/05/2001	John C. Hiserodt	IRVN001DIV2	8672

24353 7590 05/03/2005

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,823

Applicant(s)

HISERODT ET AL.

Examiner

Christopher H. Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-52, 54-60, 64-75 and 77-79 is/are rejected.
- 7) ☒ Claim(s) 53, 61-63 and 76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Re: Hiserdot *et al*
Priority Date: 29 October 1996

1. The amendment filed 12/20/2004 is acknowledged and entered into the record. Accordingly, claims 1-30 are canceled without prejudice or disclaimer, and claims are newly added.
2. Claims 31-79 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Arguments

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 31-52, 54-60, 64-75, and 77-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaffee *et al* (US Patent 6,033,674) as evidenced by Cosman *et al* (Behring. Inst. Mitt. 1988 Aug; 83:15-26 -- previously cited). Jaffee *et al* teach a method of stimulating an immune response for the purposes of treating cancer (see col. 4, lines

Art Unit: 1642

17-27) comprising the administration of an irradiated (col. 10, line 23) tumor cell line that has been modified to increase the expression of a cytokine, such as M-CSF. Jaffee *et al* further teach that the cell line can be derived from the same tissue type as a tumor in the subject (see col. 4, lines 65-66); that the tumor can be ovarian (col. 4, line 40); allogeneic (col. 2, line 36); a human cell (col. 4, line 63); histocompatibly matched (col. 2, line 35), and transduced by a viral vector (see col. 7, lines 20-35, for example). In addition, Jaffee *et al* also teach that the cell line used in the generation of an immune response against a tumor comprise a tumor associated antigen (col. 3, line 12-13, for example) and because the tumor cell line used can be derived from the same tissue as the tumor, it must therefore be autologous and expressed by the same cell. Jaffee *et al* also teaches methods of dispersal of the cell lines (see cols. 5 and 13). Moreover, because the tumor cell line administered by Jaffee *et al* expressed a M-CSF cytokine, the limitations of claim 41 are met because the claim does not preclude that the cells be different cells. Further, because M-CSF is naturally expressed as both a membrane bound and secreted cytokine (as evidenced by Cosman *et al* (teaches that M-CSF is naturally expressed as both a membrane bound and secreted cytokine), the cell line administered by Jaffee *et al* would meet the limitations of claim 46. Because the office does not have the facilities to determine if the membrane associated form is in fact expressed at a higher level than the secreted form as claimed in claim 47 or that the immune response is generated for the purposes of priming or boosting a response, in the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method using a product that appears to be the same as that of the prior art is in

Art Unit: 1642

fact different or patentably distinct. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 12/20/2004.

Conclusion

6. No claim is allowed.
7. Claims 53,61-63, and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
April 18, 2005

Jeffrey Siew
JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/28/05